UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

IMS HEALTH INCORPORATED; VERISPAN, LLC; and SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of WOLTERS KLUWER, HEALTH INC.,	:	
Plaintiffs,	:	File No. 1:07-CV-188
v.	:	(Lead Case)
WILLIAM H. SORRELL, as Attorney General of the State of Vermont,	:	
Defendant.	:	
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,	:	
Plaintiff,	:	File No. 1:07-CV-220
v.	:	(Member Case)
WILLIAM H. SORRELL, in his official capacity as Attorney General of the State of Vermont; JIM DOUGLAS, in his official capacity as Governor of the State of Vermont; and CYNTHIA D. LAWARE, in her official capacity as the Secretary of the Agency of Human Services of the State of Vermont,	:	
Defendants.	:	

MEMORANDUM OPINION AND ORDER

I. Introduction

This case is the third in a succession of challenges to legislation in New Hampshire, Maine, and Vermont intending to regulate the collection and use of data identifying health care providers' prescribing patterns. This ruling addresses multiple

constitutional challenges to sections 17, 20 and 21 of Vt. Acts No. 80 (2007), as amended by Vt. Acts No. 89 (2008) ("the Act").

For the following reasons, the Court finds the challenged sections withstand the constitutional challenges. Plaintiffs' motions for declaratory and injunctive relief as well as summary judgment (Papers 6, 61, 168) are denied. Defendants' motions for summary judgment (Papers 205, 247, 257) are denied as moot.

II. Facts

A. Introduction

In 2007, the Vermont Legislature passed Act 80 aimed at protecting public health and containing prescription drug costs. The Act included the following sections, as amended by Act 89, passed in 2008:

- Section 17 – prohibiting regulated entities from selling or using prescriber-identifiable data for marketing or promoting prescription drugs unless the prescriber consents, codified at Vt. Stat. Ann. tit. 18, § 4631;
- Section 20 – creating an evidence-based education program for health care professionals concerning the therapeutic and cost-effective utilization of prescription drugs. The program is funded by a fee paid by pharmaceutical manufacturers whose products are sold through Vermont programs, codified at Vt. Stat. Ann. tit. 18, § 4622, Vt. Stat. Ann. tit. 33, § 2004;

- Section 21 – creating a consumer fraud cause of action for advertisements printed, distributed or sold in Vermont that violate federal law, codified at Vt. Stat. Ann. tit. 9, § 2466a.[1]

Plaintiffs challenge these sections of the Act as unconstitutional.

B. Prescription Drug Industry Landscape

For background information on the prescription drug industry and the practice of detailing, please refer to the thorough and detailed description in Judge Barbadoro's opinion in IMS Health Inc. v. Ayotte, 490 F. Supp. 2d 163 (D.N.H. 2007). See also IMS Health Inc. v. Ayotte, 550 F.3d 42 (1st Cir. 2008); IMS Health Corp. v. Rowe, 532 F. Supp. 2d 153 (D. Me. 2007).

In the course of filling prescriptions, pharmacies acquire prescription information. Certain information, including the prescriber's name and address, the name, dosage and quantity of the drug, the date and place the prescription is filled and the patient's age and gender, is purchased by third parties who, after manipulating the data, sell it to customers, principally pharmaceutical companies. These third-party entities are sometimes referred to as "data mining companies." The manipulated data shows, among other things, details of

[1] The effective dates of sections 17 and 21 were extended to July 1, 2009.

physicians' prescribing patterns in terms of gross number of prescriptions and inclination to prescribe a particular drug.

Pharmaceutical manufacturers collectively spend close to $8 billion a year to market drugs directly to prescribers, employing thousands of sales representatives. The estimated total cost of marketing to Vermont prescribers approximates $10 million, not including samples[2] or direct-to-consumer advertising. Sales representatives provide "details" regarding the use, side effects and risk of interactions of the drug they are selling. For this reason, sales representatives are called "detailers." In addition to "details" and samples, representatives distribute medical literature and give small gifts[3] such as pens, notepads or lunch. Prescribers often rely

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[2] Pharmaceutical companies provide free samples of prescription drugs to prescribers. Samples are valued by prescribers because they enable them to provide medication to patients who could not otherwise afford it, and they also allow prescribers to test new medications. Both uses are valued by pharmaceutical companies because they may lead to long-term prescriptions.

[3] The Vermont Legislature also passed a law, as part of Act 80, requiring pharmaceutical manufacturers to disclose "the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional, or other marketing activities." Vt. Stat. Ann. tit. 18, § 4632(a)(1). There are exceptions, including samples for distribution to patients and de minimis gifts less than $25 in value. Id. § 4632(a)(4). This section of the Act is not challenged. In fact, PhRMA's voluntary "Code on Interactions with Healthcare Professionals" states companies should not give gifts to healthcare professionals, regardless of value, unless it helps in the treatment of disease or is educational.

on information provided by detailers because keeping current with the changing landscape of prescription drugs is time-consuming.[4]

Pharmaceutical companies use this prescriber-identifiable data (PI data) as a marketing tool. The data is used principally for "detailing." Detailing is the "face to face advocacy of a product by sales representatives" who visit health care professionals. Ayotte, 550 F.3d at 71 (Lipez, J.). Coincident with the phenomenon of "data mining," pharmaceutical industry spending on direct marketing has increased exponentially.

Pharmaceutical sales representatives detail only branded drugs. When a patent expires, competitors introduce generic bioequivalent[5] versions of the drug and detailing is no longer cost-effective. Branded drugs are not necessarily better than generic drugs, however they are usually more expensive.

Against this backdrop, a few states introduced laws restricting the use and sale of PI data for pharmaceutical marketing.

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[4] There are approximately 8,000 different prescription pharmaceutical products. Ayotte, 550 F.3d at 70 (Lipez, J.).

[5] "Bioequivalent" does not mean identical. Bioequivalent drugs are required to demonstrate an absorption rate between 80 and 125 percent of the branded drug. Variations in absorption rates among branded or generic drugs may cause different reactions, such as side effects. Absorption rates may vary between the generic and branded version of the same drug, as well as between different generic versions.

C. Laws Restricting Prescriber Identifiable Data

1. New Hampshire Law

New Hampshire passed the first statute restricting the use of prescription information in June 2006. The New Hampshire law "expressly prohibit[ed] the transmission or use of both patient-identifiable data and prescriber-identifiable data for certain commercial purposes."[6] Ayotte, 490 F. Supp. 2d at 170. The Legislature enacted the law "to protect patient and physician privacy and to save the State, consumers, and businesses money by reducing health care costs." Id. at 171. The law was passed quickly and without formal legislative findings. Id. at 177 n.12. It did not include manufacturer fees or advertising provisions.

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[6] The statute read, in pertinent part:

> Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used or sold . . . for any commercial purpose, except for the limited purposes of pharmacy reimbursement; [etc.] . . . . Commercial purpose includes . . . advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. . . .

N.H. Rev. Stat. Ann. § 318:47-f, invalidated by IMS Health Inc. v. Ayotte, 490 F. Supp. 2d 163 (D.N.H. 2007), rev'd, IMS Health Inc. v. Ayotte, 550 F.3d 42 (1st Cir. 2008).

Following a trial, New Hampshire's prescription information law was invalidated by the federal district court in April 2007 because the court determined the law violated the First Amendment. See Ayotte, 490 F. Supp. 2d at 183.

2. Maine Law

Maine followed New Hampshire's lead, passing a law in June 2007 which also restricted the use of prescription information. The Maine Legislature made express findings, outlining the state's interests and specific purposes in enacting the law, which were improving public health, maintaining costs, and protecting the privacy of patients and prescribers. 22 Me. Rev. Stat. Ann. § 1711-E(1-A, 1-B), invalidated by IMS Health Corp. v. Rowe, 532 F. Supp. 2d 153 (D. Me. 2008). Unlike the New Hampshire statute, however, the Maine law was crafted with an "opt-out" provision. Maine prescribers could elect to prevent pharmaceutical companies from using their individualized prescribing information for marketing, either to them or others. Rowe, 532 F. Supp. 2d at 165. The law operated by forbidding the sale or use of information for marketing purposes if the prescriber opted out.[7]

[7] The statute read, in pertinent part: "[A] carrier, pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection. . . ." 22 Me. Rev. Stat. Ann. § 1711-E(2-A), invalidated by IMS Health Corp. v. Rowe, 532 F. Supp. 2d 153 (D. Me. 2008).

Marketing was defined in the statute as:

Following a two-day evidentiary hearing, Maine's prescription privacy law was invalidated by the federal district court in December 2007 because the court determined that, notwithstanding the opt-out provision, the law violated the First Amendment. See id. at 183.

3. First Circuit Court of Appeals

Both the New Hampshire and Maine District Court decisions were appealed to the First Circuit Court of Appeals. See 1st Cir. Dkt. Nos. 07-1945 and 08-1248. The appeal of the Maine decision was stayed while the First Circuit decided the New Hampshire appeal in IMS Health Inc. v. Ayotte. In November 2008, the First Circuit issued its decision. IMS Health Inc. v. Ayotte, 550 F.3d 42 (1st Cir. 2008). The majority held the New Hampshire law did not violate the First Amendment because it regulated conduct and not speech. Id. at 54. However, the

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> [A]ny of the following activities undertaken or materials or products made available to prescribers or to their employees or agents related to the transfer of prescription drugs from the producer or seller to the consumer or buyer:
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> (1) Advertising, publicizing, promoting or selling a prescription drug;
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> (2) Activities undertaken for the purpose of influencing the market share of a prescription drug or the prescribing patterns of a prescriber, a detailing visit or a personal appearance;
>
> (3) Activities undertaken to evaluate or improve the effectiveness of a professional detailing sales force; or
>
> (4) A brochure, media advertisement, or announcement, poster or free sample of a prescription drug.

Id. § 1711-E(1)(F-1).

majority offered an alternative holding that, if the law implicated First Amendment rights, it is constitutional because it withstands intermediate scrutiny. Id. at 60. Judge Lipez concurred in the result, but believed the law did concern First Amendment rights in the first instance and the commercial speech restriction passed constitutional muster. Id. at 102 (Lipez, J., concurring and dissenting).

4. Vermont Law

Vermont is also engaged in an effort to control health care costs and, in June 2007, the Vermont Legislature passed "An Act Relating to Increasing Transparency of Prescription Drug Pricing and Information." Vt. Acts No. 80 (2007). In support of Act 80, the Legislature compiled a substantial legislative record, including express findings. Like the New Hampshire and Maine law, Act 80 includes a section restricting the use of prescriber-identifiable data for certain commercial uses, namely marketing. The Vermont Act differs, however, from both New Hampshire's flat ban on the sale or use of PI data for marketing and Maine's "opt-out" ban on the sale or use of PI data for marketing. Section 17 of Act 80, codified at Vt. Stat. Ann. tit. 18, § 4631(d), prohibits regulated entities from selling or using PI data for marketing purposes unless the prescriber consents – an "opt-in" feature. Pharmaceutical manufacturers and marketers are regulated entities under the Vermont law. Id.

Section 17 begins with a recitation of the Legislature's purpose in passing the law:

> It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

Vt. Stat. Ann. tit. 18, § 4631(a).

Section 17's pertinent language is found in subsection (d):

> A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records containing prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents as provided in subsection (c) of this section. Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents . . . .

Id. § 4631(d). Subsection (c) of the law contemplates that prescribers will indicate on their licensing applications or renewal forms whether they consent. Id. § 4631(c)(1).

A violation of the law constitutes a violation of the Vermont Consumer Fraud Act (VCFA). Id. § 4631(f). Each violation is a separate civil violation for which the Attorney General may seek relief. Id. Under the VCFA, if the Attorney General "has reason to believe that any person is using or is about to use any [unlawful] method, act or practice," and

determines that proceedings would be in the public interest, he may seek a temporary or permanent injunction. Vt. Stat. Ann. tit. 9, § 2458(a). In addition to injunctive relief, the violator is subject to a civil penalty of not more than $10,000 for each violation. Id. § 2461(a).

The law also includes sections imposing a manufacturer fee to be used to fund an academic detailing program and creating a consumer fraud cause of action against pharmaceutical manufacturers for Vermont advertisements that violate federal law.

D. Present Action

On August 29, 2007, Plaintiffs IMS Health Inc., Verispan, LLC, Source Healthcare Analytics, Inc. (the data vendor plaintiffs) filed a cause of action against Defendant Vermont Attorney General William H. Sorrell seeking preliminary and permanent injunctive relief prior to January 1, 2008, the initial effective date of the Act. (Paper 1.) On October 22, 2007, Pharmaceutical Research and Manufacturers of America (PhRMA) filed a cause of action against Defendants Sorrell, Jim Douglas, and Cynthia LaWare seeking declaratory and injunctive relief. PhRMA moved for a preliminary injunction on October 23. (Paper 61.) The case was consolidated with the IMS action in November 2007. PhRMA filed an amended complaint on April 29, 2008. (Paper 221.)

The parties filed cross motions for summary judgment consisting of hundreds of pages of briefing in the spring and summer of 2008. The Vermont Legislature changed the effective date of certain portions of Act 80 to July 1, 2009. The Court combined the motions for preliminary injunction and declaratory relief with a trial on the merits. Rulings on the summary judgment motions were deferred until after the bench trial. The parties agreed the Court could rule on PhRMA's challenge to section 20 of Act 80 without a hearing. (Paper 369.)

The Court held a five-day bench trial from July 28 through August 1, 2008. The parties presented testimony from numerous witnesses and introduced reams of exhibits, including the entire legislative history of Act 80. Both parties filed post-trial memoranda as well as supplemental briefs regarding relevant decisions rendered since the trial, including the First Circuit's decision in Ayotte and the Supreme Court's recent decision in Wyeth v. Levine, 129 S. Ct. 1187 (2009).

III. First Amendment Challenge to Section 17

Plaintiffs assert subsection (d) of section 17 violates the First Amendment. The First Amendment states, "Congress shall make no law . . . abridging the freedom of speech."[8] U.S. Const. amend. I. Because the First Amendment applies only where a government regulation restricts protected speech, the Court must

[8] The First Amendment is applicable to the states through the Due Process Clause of the Fourteenth Amendment.

first determine whether Section 17 restricts speech or merely conduct.

A. Section 17 Restricts Speech

The Attorney General seeks to sidestep Plaintiffs' First Amendment challenge completely by taking the position that section 17 does not regulate protected "speech." The Attorney General first argues the First Amendment does not apply to section 17 because PI data is factual information devoid of any protectable expressive quality. Supreme Court and Second Circuit precedent, however, require this Court to extend First Amendment protection to "[e]ven dry information, devoid of advocacy, political relevance, or artistic expression." Universal City Studios, Inc. v. Corley, 273 F.3d 429, 446 (2d Cir. 2001). See, e.g., Roth v. United States, 354 U.S. 476, 484 (1957) ("ideas having even the slightest redeeming social importance" are speech); Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976) (prescription drug price information is protected speech); Universal City Studios, 273 F.3d at 446-49 (computer program is speech). In particular, the Supreme Court has recognized society's "strong interest in the free flow of commercial information" even when there is no "great public interest element." Va. State Bd., 425 U.S. at 764. PI data is plainly commercial information possessing a degree, however debatable, of social importance. The Court therefore

finds prescriber identifiable data is protected "speech" under the First Amendment.

The Attorney General next contends section 17 eludes First Amendment review because it restricts only the "sale" and "use" of PI data, which constitute non-expressive conduct, but not the data's "disclosure." The Court disagrees. A restriction on disclosure is a regulation of speech, and the "sale" of PI data is simply disclosure for profit. Bartnicki v. Vopper, 532 U.S. 514, 526 (2001) (a "prohibition against disclosures is fairly characterized as a regulation of pure speech"). The fact that disclosure occurs by sale does not remove First Amendment protection. The Supreme Court has consistently protected speech "even though it is carried in a form that is 'sold' for profit." Va. State Bd., 425 U.S. at 761 (internal citation omitted).

Section 17's restriction on the use of PI data is likewise aptly described as a restriction on marketing. Section 17 mandates that "[p]harmaceutical manufacturers and . . . marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents." Vt. Stat. Ann. tit. 18, § 4631(d) (emphasis added). It is well-established that even "speech which does no more than propose a commercial transaction," like marketing or advertising, is protected under the First Amendment. Va. State Bd., 425 U.S. at 762 (internal quotation marks omitted) (advertising of

prescription drug prices is protected speech). Section 17's restriction on marketing is not immune to First Amendment review merely because it applies only when detailers use PI data. Indeed, section 17 restricts pharmaceutical detailers' protected speech by exercising control over detailers' ability to target their audience and message. U.S. West, Inc. v. FCC, 182 F.3d 1224, 1232 (10th Cir. 1999) (regulations prohibiting use of customer information for targeted marketing constitute restrictions on protected commercial speech).

The Attorney General finally argues section 17 is not subject to First Amendment review because its effect on pharmaceutical detailers' speech is "indirect." This reasoning contradicts Supreme Court precedent. The mere fact that section 17 regulates protected speech indirectly does not sweep it from the First Amendment's purview. Grosjean v. Am. Press Co., 297 U.S. 233, 250-51 (1936) (invalidating tax on publications with circulations of 20,000 or more that sold advertising because tax was merely a "deliberate and calculated" pretext for "penalizing the publishers and curtailing the circulation of a selected group of newspapers"); Minneapolis Star & Tribune Co. v. Minn. Comm'r of Revenue, 460 U.S. 575, 581-83 (1983) (holding differential taxation of the press unconstitutional due to indirect burden on First Amendment rights). In contrast, legislation regulating economic conduct

but affecting speech incidentally typically does not raise First Amendment concerns. See, e.g., Rumsfeld v. Forum for Acad. & Inst. Rights, Inc., 547 U.S. 47, 62 (2006). In this case, the Attorney General's briefs make clear the effect on speech is section 17's purpose, rather than an unplanned or subordinate side effect. In describing how section 17 will advance the State's substantial interests in protecting privacy, controlling costs, and protecting health, the Attorney General cites the following "evidence":

> Prescriber-identifiable data is used as a tool for aggressive, targeted marketing campaigns that influence doctors to prescribe new, expensive drugs. . . . Use of the data gives pharmaceutical sales representatives a powerful advantage in trying to sway doctors' prescribing practices. It allows them to target doctors [and] target messages . . . . And these techniques work, to the advantage of pharmaceutical companies . . . but to the disadvantage of doctors, the patients they treat, and the state of Vermont. Allowing doctors to prevent the use of their data for marketing . . . will reduce Vermont's spending and give Vermonters greater access to affordable health care.

(Paper 412 at 4.) Plainly, the whole point of section 17 is to control detailers' commercial message to prescribers. The Court strains to understand how section 17 would control cost and protect health without the "indirect" effect on detailers' speech. The Court therefore finds section 17 restricts protected speech and must comply with the First Amendment.

B. Section 17 Is a Commercial Speech Regulation Subject to Intermediate Scrutiny

The Court must next determine what level of scrutiny applies. Plaintiffs claim section 17 restricts speech that is fully protected under the First Amendment and therefore must survive strict scrutiny. The Attorney General contends the Court should apply Central Hudson's analytical framework for assessing governmental restrictions on commercial speech. See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980). For the following reasons, the Court finds section 17 restricts commercial speech and applies the test set out in Central Hudson.

Plaintiffs contend section 17 regulates pure speech because the sale of PI data does not "fall within the core notion of commercial speech-'speech which does no more than propose a commercial transaction.'" Bolger v. Youngs Drug Prod. Corp., 463 U.S. 60, 66 (1983) (citing Va. State Bd., 425 U.S. at 762) (internal quotation marks omitted). Plaintiffs appear to reason as follows: Speech which does no more than propose a commercial transaction is protected commercial speech under the First Amendment, therefore protected commercial speech must propose a commercial transaction.[9] Neither the Supreme Court nor the Second Circuit have endorsed this position. In fact, "various forms of speech that combine commercial and noncommercial

[9] Such reasoning is termed "denying the antecedent." It is a "formal fallacy," committed by reasoning in the form: If P, then Q. Not P. Therefore, not Q.

elements" lie "[o]utside this so-called 'core.'" Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth., 134 F.3d 87, 97 (2d Cir. 1998).

As the Court explained in Section III.A. above, PI data combines commercial and non-commercial elements. It is factual information with a degree of "redeeming social importance," Roth, 354 U.S. at 484, and also purely commercial information used "to decide whether, how, when, and where to market products." (Paper 409 at 62.) Data vendor Plaintiffs stress that PI data serves both of these purposes. They point out that PI data "substantially improves public health" by showing "professional errors of judgment that can and do cause death, [] trends . . . about the health and lifestyles of the public at large, and [] ways that [pharmaceutical manufacturers] can better serve the public with new or different products." (Paper 409 at 62.) Section 17, however, regulates the disclosure and use of PI data only when it is used in marketing – a decidedly commercial use. It does not regulate use of the data for non-commercial purposes such as "health care research," "educational communications," or "safety notices." Vt. Stat. Ann. tit. 18, § 4631(e). Moreover, "the purported noncommercial message is not so 'inextricably intertwined' with the commercial speech as to require a finding that [PI data] must be treated as 'pure' speech." Bad Frog Brewery, 134 F.3d at 97 (citing Bd. of Trustees of the State

Univ. of N.Y. v. Fox, 492 U.S. 469, 474 (1989)). Because section 17 regulates PI data only in connection with commercial speech, the Court finds analysis under Central Hudson is the proper test.

Plaintiffs next argue strict scrutiny is required because section 17 is a content-based speech restriction. The Court rejects this argument. By definition, the "Supreme Court's commercial speech doctrine . . . creates a category of speech defined by content but afforded only qualified protection . . . ." Trans Union Corp. v. FTC, 267 F.3d 1138, 1141-42 (D.C. Cir. 2001). See, e.g., City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410 (1993) (applying intermediate scrutiny to "content based" ban on news racks distributing commercial handbills but not racks distributing newspapers). Indeed, the Second Circuit has explicitly "rejected the argument that strict scrutiny should apply to regulations of commercial speech that are content-specific, [and continues to adhere] instead to the somewhat less rigorous standards of Central Hudson." Anderson v. Treadwell, 294 F.3d 453, 460 (2d Cir. 2002).

C. The Intermediate Scrutiny Test

1. Central Hudson

The intermediate scrutiny test elucidated by the Supreme Court in Central Hudson, 447 U.S. 557 (1980), applies to truthful, non-misleading commercial information that does not

promote unlawful activity. Id. at 566. Such speech can be limited only if the restriction: (1) supports a substantial government interest; (2) directly advances the asserted interest; and (3) is "not more extensive than is necessary to serve that interest." Anderson, 294 F.3d at 460-61 (citing Central Hudson, 447 U.S. at 563-66). The party seeking to uphold a commercial speech restriction bears the burden of proof. Thompson v. W. States Med. Ctr., 535 U.S. 357, 373 (2002).

2. Deference to Legislature

The Supreme Court's commercial speech cases allow "the exercise of legislative judgment." 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 508 (1996) (citation omitted). However, "a state legislature does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes." Id. at 510.

The parties have debated at great lengths the nature and amount of deference the Court should accord the predictive judgments and factual findings of the Legislature in passing the challenged sections of the Act. The Attorney General contends the Court should not usurp the Legislature's policymaking role by substituting its judgment for that of elected representatives. (Paper 412 at 9.) He argues the Court's inquiry should be limited to whether there was a reasonable basis for the Legislature's actions after the Court's evaluation of the

evidence. Id. (citing Turner Broad. Sys. v. FCC, 512 U.S. 622, 666 (1994)) [hereinafter Turner I]. Plaintiffs respond that Turner I is distinguishable from this case on three grounds: (1) Turner I is not a commercial speech case, (2) Congress had "considerable experience" in the area of regulation, and (3) the voluminous record, developed over years, included extensive studies. (Paper 409 at 46-48.)

Discussing the Turner cases,[10] Judge Lipez noted in Ayotte, "[a]lthough the contexts are different, the general principle of legislative deference also is compatible with the Court's commercial speech precedent." Ayotte, 550 F.3d at 93. The Supreme Court applied intermediate scrutiny to the act at issue in the Turner cases, noting deference was due to Congress' findings because "the institution is far better equipped than the judiciary to amass and evaluate the vast amounts of data bearing upon legislative questions." Turner II, 520 U.S. at 195. "[C]ourts must accord substantial deference to the predictive judgments" of legislative bodies. Turner I, 512 U.S. at 665 (internal citation omitted). Substantial deference does not mean predictive judgments are "insulated from meaningful judicial

[10] The Court in Turner considered whether the "must carry" provisions of the Cable Television Consumer Protection and Competition Act of 1992 violated the First Amendment. The Court issued two decisions: Turner I, holding the provisions imposed content-neutral restrictions on speech subject to intermediate scrutiny, 512 U.S. at 661-62, and Turner Broad. Sys., Inc. v. FCC, 520 U.S. 180 (1997)[hereinafter Turner II], holding the provisions were consistent with the First Amendment. Id. at 185.

review altogether;" the Court has an obligation to exercise independent judgment. Id. at 666. The Court must assure that a legislature has "drawn reasonable inferences based on substantial evidence" in formulating its judgments; not "reweigh the evidence de novo" or replace the legislature's factual predictions with its own. Id. The Court will defer to legislative findings, predictions, and judgments to the extent they are reasonable and based on substantial evidence.

3. Central Hudson Elements

Both parties agree that the data vendor plaintiffs disseminate truthful, non-misleading factual information that includes prescriber identifiable data. Therefore, the Court's analysis focuses on the substantiality of the interests asserted by the Legislature in support of section 17 and on whether the restriction on sale and use of PI data directly advances and bears an acceptable fit with the Legislature's substantial interests. Careful consideration of these issues indicates that the State has met its burden to justify section 17's limited restraint on commercial speech.

a. Substantial Government Interest

The Attorney General identifies three government interests promoted by section 17: prescriber privacy, cost containment, and protecting public heath. The law is sustainable on the State's cost containment and public health interests, which are

substantial, but prescriber privacy is not a sufficient interest to justify the law.

(1) Cost Containment and Protecting Public Health

The Legislature identified both cost containment and protecting public health as interests advanced by the law. The Attorney General contends these interests are substantial. Plaintiffs do not seriously dispute the Legislature has a substantial interest in protecting public health and safety,[11] see, e.g., Paper 409 at 51, or cost containment. Instead, Plaintiffs argue that lowering prescription drug costs may harm the public health and lead to higher healthcare costs overall because "cheaper is not always better." Id. at 53-54. This argument does not squarely address whether the interests themselves are substantial; instead it bears on whether the Legislature's attempt to curb rising prescription drug costs is wise. Healthcare costs, and prescription drug costs in particular, have escalated considerably over the past decade, easily outpacing inflation.[12] Pharmaceuticals expenses top

[11] Indeed, they could not because states have always had a substantial interest in promoting the health, safety, and welfare of their citizens.

[12] Evidence showed that while spending on prescription drugs has increased steadily, averaging near double digit percentage increases over the last decade, the number of prescriptions written has risen by only a few percentage points per year. Therefore, the prices paid for prescription drugs are increasing. (Defs. Ex. 9 at 562-63.)

Vermont's publicly-funded health insurance costs, reaching $158 million in 2006. (Defs.' Ex. 182 at 2.) As Judge Selya forcefully explains, "Fiscal problems have caused entire civilizations to crumble, so cost containment is most assuredly a substantial government interest." Ayotte, 550 F.3d at 55; see also id. at 84 (Lipez, J.) (accepting the state's interests in cost containment and quality health care as substantial). Likewise, this Court holds that Vermont's interests in cost containment and protecting public health are substantial.

(2) Prescriber Privacy

Because the Court accepts cost containment and protecting public health as substantial government interests, it need not consider the Attorney General's assertion that protecting prescriber privacy is also a substantial government interest. Cf. Ayotte, 550 F.3d at 55 (restricting analysis to cost containment interest for "simplicity's sake"); Anderson, 294 F.3d at 461 (declining to consider an asserted interest because the regulatory scheme was sustainable based on another interest).

b. Advancing the Government Interest

The Attorney General must prove section 17 advances at least one of the government's substantial interests "in a direct and material way." Edenfield v. Fane, 507 U.S. 761, 767 (1993). This showing is not satisfied by "mere speculation or conjecture." Id. at 770. The Attorney General "must demonstrate

that the harms it recites are real and that [the] restriction will in fact alleviate them to a material degree." Anderson, 294 F.3d at 462 (citing Edenfield, 507 U.S. at 770-71). Underinclusiveness of a regulation alone will not "defeat a claim that a state interest has been materially advanced." Bad Frog Brewery, 134 F.3d at 99. A regulation that makes only a "minute contribution" to advancing a substantial interest will not "be considered to have advanced the interest 'to a material degree.'" Id. (citing Edenfield, 507 U.S. at 771). Certitude, however, is not required. "A state need not go beyond the demands of common sense to show that a statute promises directly to advance an identified governmental interest." Ayotte, 550 F.3d at 55 (citing Burson v. Freeman, 504 U.S. 191, 211 (1992)).

As noted above, the Court will defer to legislative findings, predictions, and judgments to the extent they are reasonable and based on substantial evidence. Particularly in a case such as this, where the law affects a traditionally regulated area and is not yet effective, "it is all the more appropriate that we limit our scrutiny of state regulations to a level commensurate with the subordinate position of commercial speech in the scale of First Amendment values." Anderson, 294 F.3d at 463 (citing Florida Bar v. Went For It, Inc., 515 U.S. 618, 635 (1995)).

The Attorney General argues section 17 directly advances the State's substantial interests to a material degree because it limits the use of PI data in marketing, thus inhibiting sales of new prescription drugs which are more expensive than alternatives and possibly have unknown side effects and risks. (Paper 412 at 30-39.) More specifically, the Attorney General argues: (1) new drugs are not necessarily better than older drugs but are usually more expensive and may pose unknown risks and side effects; (2) detailing is only done for new drugs; (3) PI data is a marketing tool used to make detailing more effective and leads to the over-prescription of costly new drugs; and (4) the law's restriction on the use of PI data will reduce the influence of marketing leading to reduced prescriptions for new drugs, thereby trimming spending on prescription drugs and promoting public health.

Plaintiffs argue section 17 does not directly advance the State's substantial interests because the law uses remote means to accomplish its goal of protecting public health, and the Attorney General has not shown with empirical evidence that the law will reduce healthcare costs in Vermont. (Paper 409 at 55-57.)

(1) Cost Containment

The Legislature specifically found new prescription drugs have a higher cost than older drugs but do not necessarily provide additional benefits. Vt. Acts No. 80, § 1(7) (Finding 7). This finding, on its face, is not seriously disputed with regard to cost. See supra Section III.C.3.a.(1). The second proposition of Finding 7, that newer drugs often do not provide additional benefits over older drugs, was borne out in the briefing and at trial. Even Plaintiffs' witnesses' testimony supported the finding. For example, Mr. Randolph Frankel, a former employee of a pharmacy benefit manager, testified generic drugs are as effective as other drugs in the same class for most patients. Dr. Aaron Kesselheim, defendants' witness, testified many new drugs provide little benefit over older drugs.

Only new, branded drugs are detailed because the introduction of generic bioequivalents into the market renders detailing no longer cost effective. PI data is used as a tool to increase the success of detailing. (Defs.' Ex. 246 at 7481-83 (a 2004 IMS document notes purpose of PI data is "big returns" and points to how one pharmaceutical company increased its market share 86% with PI data).) The Legislature found that, coincident with the phenomenon of "data mining," the pharmaceutical industry increased spending on direct marketing to doctors by over 275%.

Act 80, § 1(18). The data provides detailers with specific information about doctors' prescribing practices, enabling them to target certain prescribers for their marketing efforts and to tailor presentations to individual prescriber styles, preferences, and attitudes. This information amplifies the influence and effectiveness of detailing, but does not add to its purported educational value. Detailers can provide medical literature and information regarding the drugs they are promoting without the benefit of PI data. The Vermont Medical Society has stated tailored marketing using PI data "is an intrusion into the way physicians practice medicine" and it creates the "possibility that representatives could exert too much influence on prescription patterns." See Act 80, § 1(20).

Detailing leads to increased prescriptions for new drugs over generic alternatives which are often more cost-effective. Research shows doctors are influenced by the marketing efforts of pharmaceutical companies. For example, doctors who attend talks sponsored by a pharmaceutical company often prescribe that company's drug more than competitors' drugs. See Tr. 704-06 (testimony of Dr. Ashley Wazana regarding various studies). Though Plaintiffs attempted to show that doctors are not influenced by marketing practices, that point is belied by the nature of the industry, plaintiffs' own documents, and scientific research. The main purpose of detailing is to increase the

number of prescriptions written for the drug being promoted. The billions spent each year by pharmaceutical manufacturers on detailing is evidence of its success. Pharmaceutical manufacturers are essentially the only paying customers of the data vendor industry. This is the strongest evidence of the important role of PI data in pharmaceutical detailing. Put simply, if PI data did not help sell new drugs, pharmaceutical companies would not buy it. The Court finds the Legislature's determination that PI data is an effective marketing tool that enables detailers to increase sales of new drugs is supported in the record.

The Legislature chose to counter the over-prescription of expensive new drugs by restricting the use of PI data in pharmaceutical marketing. PI data makes marketing of new drugs more effective – leading to over-prescription of new drugs that may not be better than a generic alternative. The Attorney General presented ample evidence that a shift in prescribing practices from new drugs to generic would result in a significant cost savings to the State. For example, Dr. Meredith Rosenthal testified that a 1% decrease in prescriptions of new patented drugs that do not yet have a generic bioequivalent, but that do have an adequate generic alternative, would lead to a $2 million cost savings to Vermont. (Tr. 954-55.) The Legislature predicted that prescribing decisions made without the covert

influence of PI data should lead to a better balance between new and generic prescriptions and an attendant cost savings. See Turner I, 512 U.S. at 665 ("Sound policymaking often requires legislators to forecast future events and to anticipate the likely impact of these events based on deductions and inferences for which complete empirical support may be unavailable."). On this record, the Court will not substitute its judgment for that of the Legislature.

Plaintiffs contend the lack of empirical evidence demonstrating the law will reduce healthcare costs is fatal. They point to testimony that to reliably evaluate the law's impact, the law would have had to be in place for almost a year or as long as five years. (Paper 409 at 56.) First, empirical evidence is not a requirement to withstand the intermediate scrutiny of Central Hudson in a case such as this. Ayotte, 550 F.3d at 55-59 (noting common sense is enough to show a law "promises directly to advance" a state's interest and holding, though there was no direct evidence, the New Hampshire law was reasonably calculated to advance its interest in reducing health care costs); Id. at 94 (Lipez, J.) (concluding the New Hampshire law materially advanced the state's interest in cost containment while acknowledging the state had no empirical data showing how much cost the law would save). Second, Vermont is one of a few states at the forefront in regulating marketing uses of PI data.

See, e.g., New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) ("a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments") (Brandeis, J., dissenting). Plaintiffs would never allow a law such as section 17 to go into effect without a fight, as demonstrated by prior legal battles in New Hampshire and Maine.[13] This reality has prevented empirical research on the law's effects. The Court will not hold the State to an unattainable burden.[14]

Plaintiffs also argue the Legislature substituted paternalism for empirical evidence. They contend the Legislature acted paternalistically by assuming "it knows best what doctors should hear and prescribe." (Paper 409 at 57.) They contend the Supreme Court has refused to uphold restrictions on speech predicated on paternalistic notions. In this situation however, the prescribers are aware of their own prescribing histories and, should they wish to be covertly influenced with PI data,[15] they may make use of the opt-in provision, thus allowing detailers to

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[13] The New Hampshire law went into effect briefly before being enjoined by Judge Barbadoro. The short period of time it was in effect was not sufficient to conduct meaningful research, as testified to by witnesses of Plaintiffs and the State.

[14] Indeed, Plaintiffs' witness, Dr. Turner, an economist, testified that he was asked to perform a study regarding PI data and its effect on marketing but could not do so.

[15] The data vendor plaintiffs all prohibit detailers from disclosing PI data to a prescriber. Tr. at 136 (IMS); Tr. at 194-95 (Verispan); Tr. at 230-31 (Source Healthcare).

retain the ability to use their PI data for marketing purposes. Cf. 44 Liquormart, 517 U.S. at 503 (noting the First Amendment requires skepticism toward laws "that seek to keep people in the dark for what the government perceives to be their own good"). Providing prescribers with a choice can hardly be deemed paternalistic.

Plaintiffs also argue PI data leads to more efficient detailing because sales representatives can focus on prescribers likely to be interested in the detailed drug because of their specialty and current prescribing habits. Without PI data, detailing would become less focused and more expensive leading to increased drug costs. PI data, however, is not necessary to determine the specialty of a doctor or whether a prescriber would be interested in a particular drug. Plaintiffs' witness, Dr. Thomas Wharton, testified that his practice could avoid sales representatives detailing drugs they do not prescribe by having assistants ask about the drugs being promoted. Also, sales representatives keep detailed information about doctors in their territories, including office hours and specialty, staff, and personal information. If sales representatives are able to track prescriber's favorite sports teams and birthdays, they can easily track a doctor's specialty.

The Attorney General has carried his burden to show that Vermont's interest in reducing health care costs, specifically

prescription drug spending, would be furthered to a material degree by section 17.

(2) Promoting Public Health

The Legislature, as explained above, also found new drugs often provided little or no benefit over older drugs and was concerned that the unrestricted use of PI data in marketing contributed to over-prescription of new drugs. The evidence supports this finding. Detailing encourages doctors to prescribe newer, more expensive and potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines. Some new drugs make important contributions to health and reduce health care spending, but others may have unknown side effects and risks. Examples are cholesterol drugs – statins – and stomach acid drugs – proton pump inhibitors – such as Nexium and Vytorin. Dr. Kesselheim testified that these new drugs did not provide a therapeutic benefit over older, very similar drugs available in generic form. In the case of Baycol, a statin, the new drug actually had fatal side-effects. Dr. Wharton testified he usually waits to prescribe a new drug until it has been on the market for awhile unless there is an obvious benefit and low risk associated with it – a situation occurring about 30% of the time in his estimation. In addition to Baycol, the Attorney General presented other examples of new drugs that were extensively prescribed but were removed from the market when serious side

effects were later discovered. The most recent and well known example is Vioxx, a pain medication that was widely prescribed but then recalled because its use led to increased risk of cardiovascular issues such as heart attack and stroke.

For patients with certain conditions, such as epilepsy, there may be medical reasons to prescribe a brand-name drug over a bioequivalent generic drug. Section 17 has no effect on doctors' ability to prescribe a brand-name drug. No evidence showed that the law will obstruct or slow the use of a new drug that provides a genuine benefit.

Plaintiffs' laundry list of alternative ways the Legislature could have advanced its substantial interest in protecting public health is irrelevant. The American Medical Association's (AMA) physician data restriction program is also not an adequate remedy for Vermont prescribers. Physicians may not know of the program: only 23% of Vermont physicians belong to the AMA – one of the lowest rates in the nation. Moreover, doctors are not the only prescribers in Vermont – other health care professionals who prescribe drugs may not avail themselves of the program. That other means to accomplish a goal exist does not affect whether the restriction on PI data in section 17 directly advances the State's interest. Different alternatives are not mutually exclusive.

As noted above, the Legislature determined detailing increases the prescription of new drugs, and the Attorney General presented evidence supporting the Legislature's determination that new drugs often confer no therapeutic benefit to patients and sometimes carry risks. Because new drugs often have no therapeutic benefit and may have unknown side effects and risks, inappropriate prescription of new drugs is harmful. The Legislature's decision to restrict the use of PI data in marketing to further their substantial interest in protecting public health is sufficiently direct and material.

c. Narrow Tailoring

To survive First Amendment scrutiny, commercial speech restrictions "need only be tailored in a reasonable manner to serve a substantial state interest."[16] Edenfield, 507 U.S. at 767 (citation omitted). The relevant inquiry is whether the

[16] Plaintiffs also challenge section 17 as an unlawful prior restraint. (Paper 169.) In the context of a commercial speech restriction, a prior restraint is evaluated under the last element of the Central Hudson test. Nutritional Health Alliance v. Shalala, 144 F.3d 220, 227-28 (2d Cir. 1998). The Court is not convinced section 17 constitutes a prior restraint because any suppression of speech occurs at the discretion of the prescribers who choose not to allow their prescribing histories to be used for marketing purposes. See United States v. Quattrone, 402 F.3d 304, 309 (2d Cir. 2005) (defining a prior restraint as a law that suppresses speech "or provides for its suppression at the discretion of government officials"). Since Plaintiffs' challenge is facial, and assuming section 17 constitutes a prior restraint, the Court would conclude section 17 is sufficiently narrowly tailored because it regulates commercial speech and pertains to health safety. Shalala, 144 F.3d at 228.

commercial speech restriction "is in reasonable proportion" to the substantial state interest served. Id.; see also Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173, 188 (1999) ("The Government is not required to employ the least restrictive means conceivable, but it must demonstrate . . . 'a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served.'"); Florida Bar, 515 U.S. at 632 ("the 'least restrictive means' test has no role in the commercial speech context").[17]

The Attorney General argues the law satisfies the narrow tailoring requirement of Central Hudson because it focuses solely on targeted marketing using PI data. (Paper 412 at 39.) Specifically, the law does not prohibit detailing and restricts the use of PI data only with respect to prescribers who do not want to have their prescribing histories used for marketing. Id. at 39-42. He also argues the proposed alternatives are irrelevant and inadequate. Id. at 42-43. Plaintiffs argue the law is "a poor fit" because it is over and under inclusive and there are "obvious alternatives" the Legislature could have chosen. (Paper 409 at 59-60.)

[17] See Judge Lipez's thoughtful analysis of recent debate regarding the "reasonable fit" standard of intermediate scrutiny. Ayotte, 550 F.3d at 96.

In Anderson, the Second Circuit upheld a New York statute and regulations restricting in-home real estate solicitations against a First Amendment challenge. The statute and regulations enabled owners in certain areas to request inclusion on a cease and desist list which then prohibited real estate licensees from soliciting the owners for listings. 294 F.3d at 457-58. The court held: "As to reasonable fit, the regulation can hardly be accused of being 'more extensive than necessary'; it is precisely co-extensive with those who are experiencing the particular harm that it is designed to alleviate." Anderson, 294 F.3d at 462.

The Vermont Legislature determined that targeted marketing by sales representatives armed with PI data leads to increased prescriptions for new drugs despite the availability of safe and effective cheaper alternatives. The Legislature seeks to limit the overprescription of new drugs to lower prescription drug costs and protect patients from unknown risks and side effects. Section 17, which restricts use of PI data in marketing to certain prescribers, is a targeted response to the harm of overprescription caused by detailers' use of PI data. The law does not prohibit the practice of detailing. Sales representatives are free to provide medical literature and information regarding the drugs they are promoting. Section 17, like the law at issue in Anderson, provides prescribers the ability to allow use of their PI data for marketing purposes if

they wish. Perfection is not required. The law is in reasonable proportion to the State's interests.

D. Vagueness and Overbreadth

Plaintiffs also challenge section 17 as unconstitutionally vague and overbroad. The parties dispute whether Plaintiffs' vagueness and overbreadth challenges are ripe. Regardless, the Court finds section 17 withstands the vagueness and overbreadth challenges on the merits.

The overbreadth doctrine, under which a party whose own activities are unprotected may challenge a statute by showing that it substantially abridges the First Amendment rights of parties not before the court, does not apply in cases involving commercial speech regulations. United States v. Caronia, 576 F. Supp. 2d 385, 402 (E.D.N.Y. 2008) (citing Bates v. State Bar of Ariz., 433 U.S. 350, 381 (1977)). As the Court has determined section 17 regulates commercial speech, the overbreadth doctrine does not apply.

The Supreme Court recently explained the vagueness doctrine is an outgrowth of the due process clause of the Fifth Amendment, not of the First Amendment. United States v. Williams, 128 S. Ct. 1830, 1845 (2008). A conviction would fail "to comport with due process if the statute under which it [was] obtained fail[ed] to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it

authorizes or encourages seriously discriminatory enforcement." Id. (citation omitted). However, "perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity." Id. (citing Ward v. Rock Against Racism, 491 U.S. 781, 794 (1989)).

"[T]he mere fact that close cases can be envisioned" does not render a statute vague. Id. at 1846. As the Court pointed out, "[c]lose cases can be imagined under virtually any statute," but that issue is addressed by the burden of proof requirement, not the vagueness doctrine. Id. (citation omitted).

Plaintiffs argue once the statute is effective, the data vendor plaintiffs' sources will not license to them and their pharmaceutical manufacturer customers will not license PI data from them "for marketing and other purposes." (Paper 409 at 69.) First, as Judge Selya pointed out, "plaintiffs' true complaint [] is that in banning this use of their data, we risk drying up the market for their services. To that concern we repeat: the First Amendment does not safeguard against changes in commercial regulation that render previously profitable information valueless." Ayotte, 550 F.3d at 53 (internal quotation and citation omitted). Second, the Attorney General points out that the "data vending" industry is organized around contractual relationships. "Covered entities" are expected to place contractual limits on nonconsensual use of the data for marketing

purposes. Contractual limits in the contracts between the data vendor plaintiffs and the covered entities from whom they receive data would protect the covered entities. Pharmaceutical manufacturers and marketers, to whom the data vendor plaintiffs sell PI data, are directly prohibited by section 17 from using PI data for marketing or promoting prescription drugs unless the prescriber has consented. The Attorney General is charged with enforcing section 17, and the Attorney General's position is that contractual limits would suffice to protect covered entities from prosecution. In such circumstances and on a facial challenge, the Court will not presume the law will create a chilling effect. See Wash. State Grange v. Wash. State Repub. Party, 128 S. Ct. 1184, 1194 (2008) (explaining deference requires a court to determine whether challenged law could possibly be implemented constitutionally). The Court finds section 17 is not unconstitutionally vague.

IV. Dormant Commerce Clause Challenge to Section 17

Data vendor Plaintiffs also claim section 17 is unconstitutional because it violates the dormant Commerce Clause. The Commerce Clause states, "The Congress shall have Power . . . to regulate Commerce . . . among the several States . . . ." U.S. Const., Art. I, § 8, cl. 3. The Supreme Court long has recognized this affirmative grant of authority to Congress also encompasses an implicit or "dormant" limitation on the authority

of the States to enact legislation affecting interstate commerce. Healy v. Beer Inst., Inc., 491 U.S. 324, 326 n.1 (1989). Data vendor Plaintiffs challenge only the section 17 provision regulating the sale of raw prescription data.[18] It states:

> A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records containing prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents . . . .

Vt. Stat. Ann. tit. 18, § 4631(d). Data vendors are not directly regulated under the statute. (Paper 340 at 2.) Rather, the statute prohibits pharmacies and other similar entities from selling the raw prescription data in the first instance if it will later be used for marketing.

The prohibited data sale often occurs via a three-step transaction that is the focus of the parties' Commerce Clause arguments. First, a pharmacy in Vermont fills a patient's prescription. The Vermont pharmacy then transmits this raw data to its parent company outside of Vermont, which may also transfer the information to other entities such as insurance companies or prescription benefit managers. The parent company, insurance company or other entity outside of Vermont then sells the

[18] PhRMA did not raise a Commerce Clause challenge to section 17's provision regulating their "use" of PI data for "marketing or promoting a prescription drug."

information to data vendors who are also located outside Vermont. For example, "IMS Health has its principal place of business in Plymouth Meeting, Pennsylvania. It has an agreement with Rite Aid, which has its principal place of business in Camp Hill, Pennsylvania, to acquire prescription information . . . including . . . prescriptions dispensed in Vermont and written by prescribers doing business in Vermont." (Paper 300 at 3-4.) According to data vendor Plaintiffs, under this scenario the ultimate sale occurs "wholly outside" Vermont, and is therefore beyond section 17's territorial reach. Id. at 4. The Attorney General argues data vendor Plaintiffs have no standing to litigate this claim and that, in any event, the claim fails on the merits.

A. Standing

The Attorney General contends data vendor Plaintiffs cannot demonstrate standing to raise a Dormant Commerce Clause challenge because section 17 does not regulate them. Standing under the Commerce Clause is not limited, however, to parties directly regulated by the statute. Rather, "[a] plaintiff must demonstrate 'a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement.'" Am. Booksellers Found. v. Dean, 342 F.3d 96, 101 (2d Cir. 2003). Data vendor Plaintiffs have shown there is a realistic danger section 17 will have "an immediate damaging effect on their

businesses." Gov't Suppliers Consolidating Servs., Inc. v. Bayh, 975 F.2d 1267, 1275 (7th Cir. 1992) (holding plaintiffs who did not engage in "backhauling" waste nonetheless had standing to challenge restriction on backhauling because of restriction's adverse effect on their businesses). The Court therefore finds the data vendor Plaintiffs have standing to assert a Commerce Clause claim.

B. Merits

A state law that regulates commerce occurring wholly outside that state's borders is invalid under the Commerce Clause. Healy, 491 U.S. at 332. This is so "regardless of whether the statute's extraterritorial reach was intended by the legislature" because the "critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." Id. at 336. "[T]he practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States . . . . Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another state." Id. at 336-37. Courts reviewing challenges to state statutes must also be mindful, however, that "[t]he dormant Commerce Clause is not a roving license for federal

courts to decide what activities are appropriate for state and local government to undertake . . . ." United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 343 (2007). Indeed, courts "should be particularly hesitant to interfere with the [state's] efforts under the guise of the Commerce Clause," where, as here, the statute involves "a field traditionally subject to state regulation." SPGGC, LLC v. Blumenthal, 505 F.3d 183, 194 (2d Cir. 2007) (quoting United Haulers, 550 U.S. at 344). With these principles in mind, the Court considers the parties' claims.

Data vendor Plaintiffs contend section 17 regulates extraterritorial conduct because "[i]t allows pharmacies located in Vermont to transfer prescriber-identifiable information . . . to their out-of-state headquarters but then prevents those out-of-state companies from contracting with the out-of-state publisher plaintiffs" to sell that information. (Paper 300 at 8.) They also note that because section 17 imposes penalties if pharmacies or similar entities "permit the use" of PI data for marketing, covered entities must place contractual limits on purchasers' downstream uses. Id. Plaintiffs argue this downstream limitation "projects the laws of Vermont into the contracts executed outside of Vermont and otherwise governed by the laws of other states . . . ." Id.

The Attorney General argues section 17 regulates strictly Vermont commerce because the statute applies only to records containing "information or documentation from a prescription dispensed in Vermont and written by a prescriber doing business in Vermont." See Vt. Stat. Ann. tit. 18, § 4631(b)(9) (defining "regulated records"). Likewise, the statute regulates only entities doing business in Vermont or licensed by Vermont. See, e.g., id. § 4631(b)(6) (defining pharmacy). According to the Attorney General, if a business like Rite Aid "does business in Vermont [and] its pharmacies are licensed in Vermont, [] it is subject to state regulation in connection with its business practices [in the state]. . . . Those regulations include restrictions on the use and disclosure of Vermont prescription records." (Paper 257-2 at 6.) The Court agrees.

"The limitation imposed by the Commerce Clause on state regulatory power is by no means absolute, and the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." Maine v. Taylor, 477 U.S. 131, 138 (1986) (internal quotation and citation omitted). The Court recognizes section 17 will affect data vendors located outside Vermont by foreclosing their ability to sell Vermont PI data that ultimately will be used for marketing to Vermont prescribers. Data vendors remain free under section 17, however, to conduct this business

in connection with all states other than Vermont. Section 17 does not regulate the sale, price or use of prescription data originating in any other state. Section 17 "regulates only information that originates in Vermont - i.e., prescriber-identifiable data from Vermont prescription records – and conduct that occurs in Vermont - i.e., . . . Vermont pharmacies [that] sell, license, exchange, or permit the use of the data, and pharmaceutical manufacturers [that] use the data to market drugs in Vermont."[19] (Paper 340 at 6.)

Vermont pharmacies cannot avoid compliance simply by routing data through a parent company's server on its way to data

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[19] Plaintiffs argue section 17 also prohibits using Vermont PI data to market to prescribers outside Vermont. The Court notes as an initial matter that it seems nonsensical, given the inherent value of PI data, to complain that detailers cannot use a Vermont prescriber's data to market drugs to a different prescriber in another state. Indeed, Plaintiffs state that "typical[ly]," pharmaceutical companies like Pfizer use PI data "to make decisions in New York about how to conduct its marketing efforts in Vermont or actually send the information into Vermont so that its sales personnel on the ground in Vermont could use it . . . to conduct their marketing efforts." (Paper 300 at 4.) In any case, the Attorney General argues section 17 applies only to uses inside Vermont, (Paper 257-2 at 9), and asks the Court to read the statute in light of the general assumption that legislation applies only within the territorial jurisdiction of the governmental body enacting it. See Small v. United States, 544 U.S. 385, 389 (2005) (recognizing general "presumption against extraterritorial application" of federal statutes); Ayotte, 550 F.3d at 63 (applying this principle to state statutes). Moreover, the Court is not inclined during pre-enforcement review to speculate about whether or how Vermont might prosecute uses of PI data outside Vermont. See Richmond Boro Gun Club, Inc. v. City of New York, 97 F.3d 681, 686 (2d Cir. 1996) (discouraging pre-enforcement "as-applied" challenges).

vendors. The Second Circuit made clear that state regulations are not rendered unconstitutional simply because a business uses the internet to conduct transactions. In SPGGC, the Second Circuit held that a Connecticut Gift Card Law controlled sales of gift cards to Connecticut consumers, even when the sales were conducted online with an out-of-state seller. 505 F.3d at 195. The court concluded out-of-state sellers were capable of applying the law only to consumers with Connecticut addresses. Thus, the "practical effect" of the Gift Card Law was to control only Connecticut-related commerce. Id. Like Connecticut's Gift Card Law, section 17 controls only Vermont-related commerce by "[i]mpos[ing] restrictions on the use of data in Vermont records by Vermont businesses." (Paper 340 at 7.) Because these records are easily identified, businesses outside Vermont would have no difficulty limiting section 17's application.

Plaintiffs contend this case is controlled by American Booksellers Foundation for Free Expression v. Dean, 202 F. Supp. 2d 300 (D. Vt. 2002), aff'd in part and modified in part, 342 F.3d 96 (2d Cir. 2003). In Dean, website operators challenged a state law prohibiting transfer of sexually explicit material to minors. The Second Circuit held the law violated the Commerce Clause because "[a] person outside Vermont who posts information on a website . . . cannot prevent people in Vermont from accessing the material. . . . This means that those outside

Vermont must comply with [the statute] or risk prosecution by Vermont." 342 F.3d 103. The Second Circuit's holding, as in SPGGC, turned on whether the regulation was capable of distinguishing in-state and out-of-state targets. Vermont prescription records are perfectly distinguishable from other states' records, and the Court sees no risk that section 17 will control PI data sales for states other than Vermont.

Finally, Plaintiffs argue section 17 is similar to statutes invalidated in price-tying cases. See, e.g., Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935) (invaliding New York statute that had the practical effect of regulating price of milk in other states); Pharm. Research & Mfrs. of Am. v. Dist. of Columbia, 406 F. Supp. 2d 56 (D.D.C. 2005) (invalidating District of Columbia statute that had the practical effect of regulating price of drugs in other states). These cases are inapposite. The statutes at issue in the price-tying cases "project[ed] [their] legislation into [other states] by regulating the price to be paid in that state for [goods] acquired there." Baldwin, 294 U.S. at 521. The Supreme Court struck down the statutes because they were merely a guised attempt to "mitigate the consequences of competition between the states." Id. at 522. Section 17 is neither discriminatory nor protectionist, and the Court finds Plaintiffs' comparisons unpersuasive. Accordingly,

the Court finds section 17 is permissible under the Commerce Clause.

V. First Amendment Challenge to Section 20

PhRMA moves for summary judgment contending section 20 violates the First Amendment because it imposes a fee on prescription drug manufacturers to fund an "evidence-based education" program that will "spread a message into which PhRMA member companies have no input."[20] (Paper 168 at 2.) Defendants also moved for summary judgment with respect to section 20. (Paper 205.) Defendants contend the manufacturer fee and its intended use is constitutional. Id. at 1. The parties agreed to allow the Court to decide this issue on the pleadings without a hearing. (Paper 369.)

Section 20, in part, creates an evidence-based prescription drug education program that provides information and education on the therapeutic and cost-effective utilization of prescription drugs to prescribers. Pharmaceutical manufacturers whose products are sold through Vermont programs fund the program by paying fees. Section 20 is codified at Vt. Stat. Ann. tit. 18, § 4622 and Vt. Stat. Ann. tit. 33, § 2004.

PhRMA's challenge to the evidence-based education program is disfavored from the outset. The challenge is a facial challenge because it is brought before the program has been implemented.

[20] The data vendor plaintiffs do not challenge the constitutionality of section 20.

Bowen v. Kendrick, 487 U.S. 589, 600 (1988). Facial challenges fail if a statute has a "plainly legitimate sweep." Wash. State Grange, 128 S. Ct. at 1190 (citing Washington v. Glucksberg, 521 U.S. 702, 739-40 (1997) (Stevens, J., concurring)). On a facial challenge, courts may not look beyond a statute's facial requirements and must be careful not to speculate about "hypothetical" or "imaginary" cases. Id.; see also Field Day, LLC v. County of Suffolk, 463 F.3d 167, 174 (2d Cir. 2006) ("A 'facial challenge' to a statute considers only the text of the statute itself, not its application to the particular circumstances of an individual.") (citation omitted). The Supreme Court has noted facial challenges are disfavored for a multitude of reasons, such as "the risk of premature interpretation of statutes on the basis of factually barebones records." Wash. State Grange, 128 S. Ct. at 1191 (internal quotation and citation omitted).

First Amendment challenges to allegedly compelled expression may fall into one of a few categories. PhRMA's challenge to one of the intended uses of the manufacturer fee is not a "compelled-speech" case because PhRMA's member companies are not obliged personally to express a message imposed by the government with which they disagree. See Johanns v. Livestock Mktg. Ass'n, 544 U.S. 550, 557 (2005). The issue is whether PhRMA's challenge falls into the "compelled-subsidy" category because PhRMA members

are required by the government to subsidize a message expressed by a private entity with which they disagree, a type of challenge that has been sustained,[21] or whether it falls into the "government-compelled subsidy of the government's own speech" category, a type of challenge that has been rejected. Id. at 557, 562.

PhRMA argues the manufacturer fee provision violates the First Amendment by compelling PhRMA member companies to subsidize speech with which they do not agree and have no input. PhRMA's argument misses the mark because the government may compel subsidies to pay for speech to which one objects. Johanns, 544 U.S. at 559 ("Compelled support of government - even those programs of government one does not approve - is of course perfectly constitutional . . . And some government programs involve, or entirely consist of, advocating a position.") (internal quotation marks omitted) (citation omitted). "The government, as a general rule, may support valid programs and policies by taxes or other exactions binding on protesting parties. Within this broader principle it seems inevitable that funds raised by the government will be spent for speech and other expression to advocate and defend its own policies." Id.

[21] PhRMA's reliance on United States v United Foods, Inc., 533 U.S. 405 (2001) is misplaced. The Court struck down the advertising program but its holding was limited by the fact that the speech at issue was presumed to be private speech because the government did not argue the government speech doctrine. Id. at 416-17.

(internal quotation marks omitted) (citation omitted). The issue, as noted, is whether the speech which PhRMA member companies are compelled to subsidize is that of private parties or of the government.

PhRMA argues the speech at issue is not "government speech" because "private interests would shape and effectively control the content of the evidence-based standards of care created as part of the evidence-based education program funded by the Manufacturer Fee." (Paper 231 at 2.) They point to the "Blueprint for Health's" provider practice working group as the private interests that will develop the standards. Id. at 2-3. The legislation creating the evidence-based education program, however, requires the State Department of Health, in collaboration with other state entities, to establish the program. Vt. Stat. Ann. tit. 18, § 4622(a)(1); see also id. § 4621(1). The statute provides, to "the extent practicable," the education program "shall use the evidence-based standards developed by the blueprint for health." Id. § 4622(a)(1). The blueprint is an existing entity that focuses on chronic care, id. § 701(1), and is headed by an appointed state official, id. § 702.

PhRMA's main argument rests on the extent to which the evidence-based standards used in the program will be developed by the blueprint for health. PhRMA focuses on the infrastructure of

the blueprint which includes groups consisting of various private actors. Because it does not depend on a facial requirement of the manufacturer fee or evidence-based education program, this argument is misplaced. Instead PhRMA's argument focuses on the possibility the program will be implemented with an unconstitutional amount of private input and the internal machinations of the blueprint. The Department of Health is responsible for the program the manufacturer fee will fund. The extent to which the program references the applicable standards created by the blueprint, which may have been influenced by private actors, is irrelevant.[22] See Johanns, 544 U.S. at 562 (holding where "the government sets the overall message to be communicated and approves every word that is disseminated, it is not precluded from relying on the government-speech doctrine merely because it solicits assistance from nongovernmental sources in developing specific messages.").

Here, as in Johanns, the Vermont Legislature has established the overarching message and some of its elements, and left the development of the details to a state agency and the Secretary of

[22] It is possible that the program will include an amount of private influence that a court could find would prohibit the Attorney General from defending its constitutionality with the government speech doctrine. See Wash. State Grange, 128 S. Ct. at 1193. Conversely, it is also possible none of the standards developed by the blueprint will be appropriate for use in the new program. PhRMA or any one of its member companies may be able to challenge the law in an as-applied challenge should it feel the program, once implemented, is unconstitutional.

Human Services, who in turn may consider material developed by an entity headed by a state official. See Johanns, 544 U.S. at 561.

Additionally, section 20 is "germane" to a "broader regulatory scheme." Id. at 558-59. PhRMA challenges only one small part of this section of the law – the use of a portion of the manufacturer fees collected to fund an evidence-based prescription education program. The section has a "plainly legitimate sweep" as it allocates the manufacturer fee predominately to other portions of Act 80, including the support of the disclosure obligations imposed by Vt. Stat. Ann., tit. 18 § 4632 and § 4633 and the government's enforcement of section 17, which the Court also upholds against constitutional challenge.

PhRMA's current challenge is a facial one and the Court will not strike down section 20, or any part of it based on speculation and a factually barebones record. The Vermont Legislature enacted section 20 and the Court assumes the evidence-based education program can be implemented in a constitutional manner. On its face, section 20 does not run afoul of the Constitution.

VI. PhRMA's Commerce Clause and Preemption Challenges to Section 21

Plaintiff PhRMA next advances a Commerce Clause and preemption challenge to section 21(c) of Act 80. Section 21(c) creates a cause of action under Vermont's Consumer Fraud Act for

prescription drug advertisements that violate federal law. Section 21(c) provides:

> It shall be a prohibited practice under section 2453 of this title for a manufacturer of prescription drugs to present or cause to be presented in the state a regulated advertisement if that advertisement does not comply with the requirements concerning drugs and devices and prescription drug advertising in federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202.

Vt. Stat. Ann. tit. 9, § 2466a(c)(1). PhRMA seeks a ruling that the statute is facially unconstitutional and an injunction preventing its enforcement.

A. Commerce Clause Challenge

PhRMA argues section 21(c) violates the Commerce Clause because it "has the practical effect of requiring out-of-state commerce to be conducted at [Vermont's] discretion." Am. Booksellers Found. v. Dean, 342 F.3d 96, 102 (2d Cir. 2003) (citing Brown & Williamson Tobacco Corp. v. Pataki, 320 F.3d 200, 208-09 (2d Cir. 2003)). PhRMA concludes section 21(c) will, in effect, regulate prescription drug advertising in all states because its members typically advertise through national television and print media, and these advertisements could ultimately make a downstream appearance in Vermont. Thus, PhRMA members would need to comply with section 21(c) for all national advertising or risk prosecution if a national advertisement makes its way to Vermont. The Attorney General responds that,

irrespective of section 21(c), PhRMA's advertisements must comply with federal law and regulations in all jurisdictions. Thus, section 21(c) on its face imposes no additional "Vermont" standards.

The key to resolving the parties' competing arguments is PhRMA's fundamental premise that section 21(c) will impose substantive standards different from federal law and regulations. This premise derives from PhRMA's prediction that Vermont courts will likely interpret federal law differently than the Food and Drug Administration (FDA) – the federal agency that promulgates and enforces regulations based on federal prescription drug advertising law.

As noted previously, the Court may not engage in such speculation on a facial challenge. Wash. State Grange, 128 S. Ct. at 1190 (on facial challenge, courts "must be careful not to go beyond the statute's facial requirements and speculate about 'hypothetical' or 'imaginary' cases.") (citation omitted); see also Field Day, LLC, 463 F.3d at 174 (during a facial challenge a court "considers only the text of the statute itself"). Nothing in section 21(c)'s plain language suggests Vermont courts will impose different or additional standards on pharmaceutical advertising compared to federal law. Plaintiff's pre-enforcement facial challenge here is premature. PhRMA's members may properly raise this claim as a defense, however, if

and when a member is prosecuted for violating section 21(c). The courts will then have "occasion to construe the law in the context of actual disputes," and avoid "the risk of premature interpretation . . . on the basis of factually barebones records." Wash. State Grange, 128 S. Ct. at 1190-91 (internal quotation marks and citation omitted). Accordingly, the Court finds section 21(c) is facially permissible under the Commerce Clause and declines to issue an injunction against its enforcement.

B. Preemption

PhRMA next argues section 21(c) is preempted because it conflicts with the very federal law it seeks to enforce. PhRMA's rationale again stems from the premise that a state court might impose "potentially different" or "broader" interpretations of federal drug advertising law. These interpretations, PhRMA contends, would interfere with the FDA's specific, comprehensive regulation of drug advertising. The Attorney General argues PhRMA's preemption challenge fails because it is based entirely on impermissible speculation about how Vermont courts will construe the statute and because the Supreme Court has repeatedly sanctioned state law remedies for conduct that violates federal law. The Court agrees.

"[B]ecause the states are independent sovereigns in our federal system, [courts] have long presumed that Congress does

not cavalierly pre-empt state-law causes of action." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996). This is particularly true where, as here, "Congress has legislated in a field which the States have traditionally occupied." Id. (internal quotation and citation omitted). Accordingly, state law is deemed preempted due to conflict with federal law only "where compliance with both federal and state regulations is a physical impossibility . . . or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992) (internal quotation marks and citations omitted). "The conflict standard for preemption is strict" and requires a "clear demonstration of conflict." Madeira v. Affordable Hous. Found., Inc., 469 F.3d 219, 238 (2d Cir. 2006) (internal quotation marks and citation omitted). PhRMA has failed to demonstrate clearly the conflict between federal law and section 21(c).

First, the Court sees nothing in section 21(c)'s plain language evincing a clear conflict with the purposes and objectives of federal drug advertising law. PhRMA predicts Vermont state courts will create a different, potentially broader, reading of federal drug advertising law that will conflict with federal regulation. This preemption claim fails for the same reason PhRMA's Commerce Clause fails – it is based

on improper speculation. Supreme Court precedent makes clear that facial challenges must be resolved solely on the basis of the statute's facial requirements, not on speculation, assumption, or prediction. This is particularly true here where the courts have had no occasion to "accord the law a limiting construction to avoid constitutional questions." Wash. State Grange, 128 S. Ct. at 1190. Section 21(c)'s language does not necessarily require a state court to decide, in the first instance, whether an advertisement violates federal law. As the Attorney General notes, Vermont courts could interpret section 21(c) in any number of ways. For example, a Vermont court "might allow a claim to proceed only if the FDA had already determined the advertising violated federal law." (Paper 257-2 at 23.) Thus, it is certainly not a foregone conclusion that Vermont state courts will interpret federal drug advertising requirements differently or more broadly than the FDA. Indeed, PhRMA acknowledges "a court might construe § 21(c) in a manner that avoided these effects." (Paper 303 at 2.)

Accepting the statute's requirements on its face, as this Court must, section 21(c) simply creates an additional remedy for violations of federal prescription drug advertising law. The Court finds, absent federal statutory language indicating the contrary, these remedies are constitutionally permissible.[23]

[23] The Court notes that the Supreme Court's recent decision in Wyeth v. Levine, 129 S. Ct. 1187 (2009), while not

The preemption clause does not "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements." Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1011 (2008) (citing Lohr, 518 U.S. at 495). Rather than frustrating federal objectives, such remedies "merely provide[] another reason for manufacturers to comply with identical existing requirements under federal law." Lohr, 518 U.S. at 495 (internal quotation marks omitted). The Court therefore finds section 21(c) is not preempted by federal drug advertising law and declines to enter an injunction against the statute's enforcement.

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directly on point, bolsters this proposition. In Wyeth, the Court reaffirmed the strong presumption against preemption of state law causes of action by rejecting a stronger argument for preemption than PhRMA presents here. The Court held that state law product liability claims challenging the adequacy of manufacturer's labeling were not preempted by federal law. Thus, in Wyeth, the parties put squarely before the Court the question of whether state tort law imposes different requirements from those imposed by the FDA, and, if so, whether those standards are preempted because they are an obstacle to the FDA's statutory mission. Id. at 1201-04. The Court held the tort action at issue in that case was not preempted, despite the fact that different or additional requirements may be imposed. In contrast, section 21(c), on its face, imposes liability only for advertisements that violate federal requirements. In light of the Supreme Court's holding in Wyeth, the Court declines to find section 21(c) preempted when the requirements it imposes merely "duplicate" or "parallel" federal requirements. See Medtronic, 518 U.S. at 495.

VII. Conclusion

For these reasons, Plaintiffs' motions for declaratory and injunctive relief as well as summary judgment (Papers 6, 61, 168) are DENIED. Defendants' motions for summary judgment (Papers 205, 247, 257) are DENIED as moot. Defendants' Motion in Limine Seeking Judicial Notice of Certain Documents Pursuant to the Doctrine of 'Legislative Facts' (Paper 290)is DENIED as moot.

SO ORDERED.

Dated at Brattleboro, Vermont, this 23rd day of April, 2009.

/s/ J. Garvan Murtha
J. Garvan Murtha
United States District Judge